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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,470	04/06/2001	Richard W. Layne	41914.551	6760

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IP Section

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EXAMINER

NGUYEN, CAMTU TRAN

ART UNIT

PAPER NUMBER

3772

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/828,470	Applicant(s) LAYNE ET AL.	
	Examiner Camtu T. Nguyen	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,12,23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,12,23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3772

DETAILED ACTION

Response to Amendment

This Office Action is responding to applicant's amendment filed on 11-10-2008. Claim 24 is newly added.

No claim has been amended.

Claims 1, 4, 12, 23, and 24 are now present in this application.

Applicant remarked that the previous Office Action relied on Figure 4 and then Figure 5K(l) to address the claim's limitation. Such remarks are noted and acknowledged, particularly they convey unclear and even confusing on the "distal end" point. Therefore, the previous interpretation has been withdrawn.

The claims, however, are rejected based on the following interpretation.

Please note that the Examiner's interpretation is based on the guidance provided by applicant's Figure 2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 12, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al (U.S. Patent No. 6,248,110). Reiley et al discloses in Figures 1 and 2 a

vertebral body (26) includes an exterior forms from compacted cortical bone (28) which encloses an interior volume (30) of cancellous bone (32).

With regards the extension protruding from the circumferential wall and beyond the distal end, according to applicant's the specification on page 15 lines 6-7, the extension is the platform, structurally. In addition, the specification on page 15 lines 16-17 discloses the platform (220) could be formed integrally with the hollow member (210), thus, for purposes of broad interpretation of the latter disclosure, it is reasonable for one skilled in the art to interpret the Reiley's Figure 5k(1) is consistent with applicant's specification. Furthermore, applicant's Figure 2, tool (200) comprising a distal end (250), an extension/platform (220) protrudes from tool's (200) wall and beyond the distal end (250). Applicant's Figure 2 illustrates the distal end (250) is closer to the tool's (200) proximal end than the extension/platform (220). See illustration below.

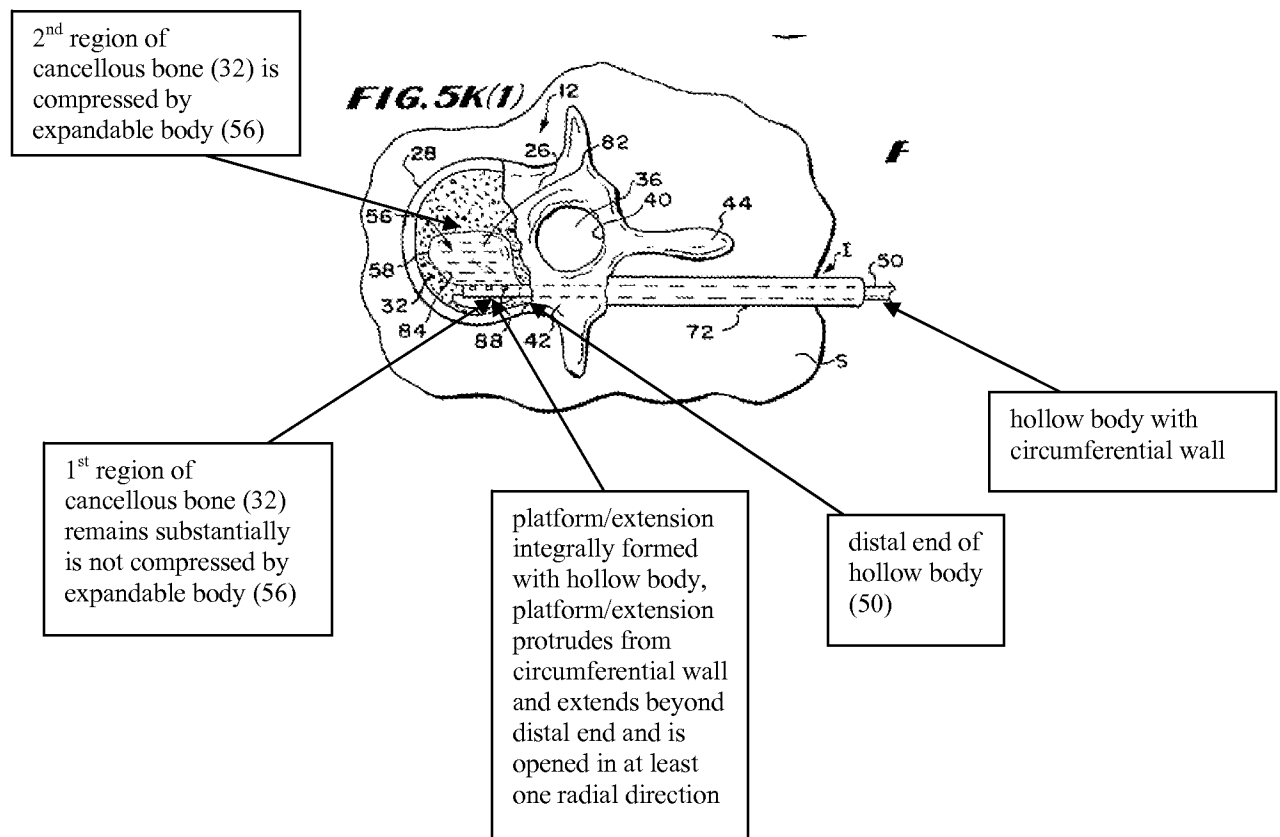


Figure 5K(1) illustrates the catheter (50) introduced into the interior volume (30) occupied in the cancellous bone (32) and the expandable body (56) expanding on one side of the distal end of the catheter (50).

Figure 5K(1) illustrates the platform/extension induce the expandable body (56) from expanding in more than one direction and expanding from the distal end towards the platform/extension. Figure 7 illustrates the injector tip (90) occupying in cavity (84) while the expandable body (56) collapses and the injector tip (90) injects filler material into the cavity (84).

With regards to claim 12, bone filling material, such as artificial bone substitute or flowable synthetic bone material or methyl methacrylate bone cement is known in the art of bone filling.

With regards to the 5th step in claim 1 reciting the platform "serving as a barrier to induce the expandable structure to expand away from the platform in the at least one radial direction to compress the second region of the cancellous bone, while the first region of the cancellous bone remains substantially not compressed", the Reiley et al's extension/platform (see illustration above) would serve as a barrier for purposes of inducing the expandable body (56) to expand away from the extension/platform in one radial direction to compress the 2nd region of cancellous bone (32) while the 1st region remains substantially not compressed.

With regards to claim 24, Figure 5K(l) of the Reiley et al illustrates the extension/platform (see illustration above) extends beyond the catheter tube (50) from only a circumferential portion of the catheter tube's (50) circumferential wall, particularly when the extension/platform extends at central point of hole (88), thereby, rendering the

Art Unit: 3772

extension/platform extending from only a circumferential portion of the catheter tube's (50) circumferential wall and not the entire circumferential wall.

The recitation "a method" has not been given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. *Kropa v. Robie*, 88 USPQ 478 (CCPA 1951).

Clearly, the illustration of Reiley et al's Figure 5K(l) interpreted above discloses applicant's invention.

The Reiley et al device would perform steps recited in method claim 1.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3772

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Camtu T. Nguyen/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772